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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,061	03/29/2006	Mitsuhiro Haraguchi	P28015	9213
7055 7590 11/02/2007 GREENBLUM & BERNSTEIN, P.L.C. 1950 ROLAND CLARKE PLACE RESTON, VA 20191			EXAMINER ROBERTS, LEZAH	
			ART UNIT 1614	PAPER NUMBER
			NOTIFICATION DATE 11/02/2007	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

gbpatent@gbpatent.com  
pto@gbpatent.com

# Office Action Summary

Application No.

10/538,061

Applicant(s)

HARAGUCHI ET AL.

Examiner

Lezah W. Roberts

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 21 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 15-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 15-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>23 Aug 2007</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

This Office Action is in response to the Request for Continued Examination filed August 21, 2007. All previous rejections have been withdrawn unless stated below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Claims***

#### **Claim Rejections - 35 USC § 102 – Anticipation (Previous Rejection)**

1) Claims 1-14 were rejected under 35 U.S.C. 102(b) as being anticipated by Takeuchi et al. (US 5,624,962). The rejection is maintained and applied to claims 15-21.

Applicant argues Takeuchi is unable to anticipate the subject matter of any of the present claims because they are apparently not suited for injection in oral surgery or dental treatment. Further, there is no indication in Takeuchi that the compositions disclosed there in may have an osmotic pressure ratio of about 0.8 – 1.3. This argument is not persuasive.

The compositions may be used in the oral cavity and are aqueous liquid compositions and therefore can be delivered by injection into the oral cavity for dental treatment. Applicant has not specified what type of injections, such as parenteral, the compositions are. The compositions of the reference may be delivered, per se, into the periodontal pocket for dental treatment or possibly injected into the cavity at the site of an extracted tooth with a syringe, which makes them injectable compositions.

**Claim Rejections - 35 USC § 102 – Anticipation (New Rejection)**

1) Claims 15-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Busciglio (US 4,748,022).

Busciglio discloses compositions comprising diphenhydramine and lidocaine, which are formulated into aqueous solutions. The compositions are used to treat oral conditions (see Abstract). In regards to being able to inject the compositions, the compositions are liquid compositions (col. 5, lines 1-2) and are therefore injectable. The amount of diphenhydramine ranges from about 0.06% to 0.09%. The amount of lidocaine HCl ranges from 0.5% to 0.7% (col. 4, lines 30-37), which encompasses claim 21 because the amount of diphenhydramine includes 1 tenth the amount of lidocaine which is encompassed by the recitation of 0.1 g of diphenhydramine to 1 g of lidocaine in instant claim 21. The reference anticipates the instant claims insofar as it discloses an injectable composition comprising a local anesthetic and an antihistamine.

2) Claims 15-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Thut et al. (US 5,505,922).

Thut et al. discloses local anesthetic compositions for injections. The compositions may comprise a local anesthetic such as lidocaine (lidocaine hydrochloride) and prilocaine and antihistamine-like anesthetics such as benadryl (diphenhydramine hydrochloride). These anesthetics can be present in the anesthetic pharmaceutical combination alone or as a mixture of two or more thereof (col. 3, lines

Art Unit: 1614

40-50). The compositions may additionally comprise sodium ions sufficient for body fluid isotonicity (col. 4, lines 22-30). The local anesthetics are formulated as 0.5 wt. % to 5.0 wt % of the solutions (col. 3, lines 66-67). The intended use of the compositions carries no weight in determining patentability because the compositions of the reference, comprising a mixture of anesthetic and antihistamine, are substantially the same as the compositions of the instant claims. That being said the compositions of the reference should be a suitable injection in oral surgery or dental treatment because the two compositions are substantially the same and are also suitable for injection to a patient. The reference anticipates the instant claims insofar as it discloses an injectable composition comprising an anesthetic and an anti-histamine.

#### **Claim Rejections - 35 USC § 103 – Obviousness (New Rejection)**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 15-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thut et al. (US 5,505,922).

The reference is discussed above in the anticipation section. The reference differs from the instant claims insofar as it does not disclose the osmotic pressure ratio or the anti-histamine amount to anesthetic amount of 0.1g to 10g of anti-histamine to 1g of anesthetic.

Normally, changes in result effective variables are not patentable where the difference involved is one of degree, not of kind; experimentation to find workable conditions generally involves the application of no more than routine skill in the art. In re Aller 105 USPQ 233, 235 (CCPA 1955). Claim 21 reads on a 1:1 ratio, therefore it would have been obvious to one of ordinary skill in the art to use a 1:1 ratio of anti-histamine and anesthetic motivated by the desire to obtain optimal efficacy to treat a

Art Unit: 1614

patient and to also use equal parts of each component when the two are used together, as supported by cited precedent.

In regards to the osmotic pressure ratio, it would have been obvious to one of ordinary skill in the art to have adjusted the isotonicity of the composition to achieve optimal diffusion of the compositions into the patients system, as supported by cited precedent.

Claims 15- 34 are rejected.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lezah W. Roberts whose telephone number is 571-272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1614

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lezah Roberts  
Patent Examiner  
Art Unit 1614



Frederick Krass  
Primary Examiner  
Art Unit 1614

